

§ 522.1004

(2) *Sponsor*. See 059521 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) *Dosage*. 12.5 units of follicle stimulating hormone twice a day for 3 days (a total of 75 units). To effect regression of the corpus luteum, prostaglandin should be given with the 5th dose.

(ii) *Indications for use*. For induction of superovulation in cows for procedures requiring the production of multiple ova at a single estrus.

(iii) *Limitations*. For intramuscular use in cows that are not pregnant and have a normal corpus luteum. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications*. The drug is a lyophilized pituitary extract material. Each 10-milliliter vial contains an amount equivalent to 50 milligrams of standard porcine follicle stimulating hormone and is reconstituted for use by addition of 10 milliliters of 0.9 percent aqueous sodium chloride solution.

(2) *Sponsor*. See 063112 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) *Dosage*. Cattle and horses, 10–50 milligrams; sheep and swine, 5–25 milligrams; dogs, 5–15 milligrams.

(ii) *Indications for use*. The drug is used as a supplemental source of follicle stimulating hormone where there is a general deficiency in cattle, horses, sheep, swine, and dogs.

(iii) *Limitations*. Administer intramuscularly, subcutaneously, or intravenously. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 47377, Sept. 9, 1993, as amended at 62 FR 62242, Nov. 21, 1997]

§ 522.1004 Fomepizole.

(a) *Specifications*. Two vials, one containing 1.5 grams fomepizole (1.5 milliliter of 1.0 gram fomepizole per milliliter sterile aqueous solution), and one vial containing 30 milliliters of 0.9 percent sodium chloride injection USP (as a diluent).

(b) *Sponsor*. See 062161 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. 20 milligrams per kilogram initially, 15 milligrams per kilogram at 12 and 24 hours, and 5 milligrams per kilogram at 36 hours.

21 CFR Ch. I (4–1–02 Edition)

(2) *Indications for use*. As an antidote for ethylene glycol (antifreeze) poisoning in dogs who have ingested or are suspected of having ingested ethylene glycol.

(3) *Limitations*. Administer intravenously. For use by or on the order of a licensed veterinarian.

[61 FR 68147, Dec. 27, 1996]

§ 522.1010 Furosemide.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) of furosemide diethanolamine.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000010 for use as in paragraphs (d)(1) and (d)(2)(ii) of this section.

(2) No. 000864 for use as in paragraph (d)(2)(ii) of this section.

(3) No. 057926 for use as in paragraphs (d)(1), (d)(2)(i), and (d)(3) of this section.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*. 1.25 to 2.5 mg per pound (lb) body weight once or twice daily, intramuscularly or intravenously.

(ii) *Indications for use*. For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(2) *Horses*—(i) *Amount*. 250 to 500 mg per animal once or twice daily, intramuscularly or intravenously.

(A) *Indications for use*. For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency, and acute noninflammatory tissue edema.

(B) *Limitations*. Do not use in horses intended for food.

(ii) *Amount*. 0.5 mg/lb body weight once or twice daily, intramuscularly or intravenously.

(A) *Indications for use*. For treatment of acute noninflammatory tissue edema.

(B) *Limitations*. Do not use in horses intended for food.

(3) *Cattle*—(i) *Amount*. 500 mg/animal once daily, intramuscularly or intravenously; or 250 mg/animal twice daily